

K030649

MAY 22 2003

510(K) Summary

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(K) number is: Unknown

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
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Contact: Name: Lakshmi Anne
Title: Director of Product Development

Summary date: February 27, 2003

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): DRI[®] Cotinine EIA Assay

Name (usual): Cotinine Assay

Classification: Cotinine Enzyme Immunoassay has been placed in Class II (MKU) by the Bureau of Medical Devices.

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

DRI[®] Cotinine EIA Assay is substantially equivalent to OTI AUTO-LYTE[®] Cotinine EIA Assay (OraSure Technologies, Inc, Bethlehem, PA), cleared under premarket notification K072481.

DRI[®] Cotinine EIA Assay is identical or similar to its predicate in terms of intended use, method principle, risk to the patient, and clinical performance.

Description of Device (21 CFR 807.92 (a)(4))

The DRI[®] Cotinine EIA Assay is a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies, which can detect cotinine drugs in urine. The assay is based on competition between a drug labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme, and free drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH causing a decrease in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Intended Use (21 CFR 807.92 (a)(5))

“The DRI[®] Cotinine Enzyme Immunoassay is intended for the Qualitative and Semi-Quantitative determination of Cotinine in human urine at a cutoff level of 500 ng/mL. This assay is intended for in vitro diagnostic use only. The assay is intended as an aid in the detection of cotinine after use or exposure to tobacco products.”

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and differences between DRI[®] Cotinine EIA Assay and the predicate device follows.

Comparison Table:

AUTO-LYTE[®] Cotinine EIA (K072481) and DRI[®] Cotinine EIA Assay

Device Name	AUTO-LYTE [®] Cotinine EIA (K072481)	DRI [®] Cotinine EIA Assay
Indications for Use	“The OraSure Technologies, Inc. (OTI) AUTO-LYTE [®] Cotinine EIA is a homogeneous immunoassay intended for the Qualitative and Semi-Quantitative analysis of cotinine in human urine. Cotinine is a metabolite of nicotine, and the OTI kit is used as an aid in the detection of cotinine after use of tobacco products or other products containing nicotine. <i>FOR IN VITRO DIAGNOSTIC USE.</i> ”	“The DRI [®] Cotinine Enzyme Immunoassay is intended for the Qualitative and Semi-Quantitative determination of Cotinine in human urine at a cutoff level of 500 ng/mL. This assay is intended for in vitro diagnostic use only. The assay is intended as an aid in the detection of cotinine after use or exposure to tobacco products.”
Method Principle	The OTI AUTO-LYTE [®] Cotinine EIA is a homogeneous enzyme immunoassay used for the analysis of cotinine in urine. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenase (G6PDH) for antibody binding sites. Enzyme activity decreases upon binding to the antibody; free drug in the sample is proportional to enzyme activity. Active enzyme converts oxidized nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance change that is measured spectrophotometrically at 340 nm.	The DRI [®] Cotinine Assay is a liquid, ready-to-use homogeneous enzyme immunoassay. The assay is based on competition between cotinine labeled with glucose-6-phosphate dehydrogenase (G6PDH) enzyme and free cotinine from in the sample for a fixed amount of cotinine-specific antibody binding sites. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.
Components	- Reagent A - Reagent B	- Antibody/Substrate Reagent - Enzyme Conjugate Reagent
Anti-Cotinine Antibody	Sheep Polyclonal	Mouse Monoclonal
Risk to patient	Not included in package insert.	This assay provides only a preliminary analytical result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical

Device Name	AUTO-LYTE [®] Cotinine EIA (K072481)	DRI [®] Cotinine EIA Assay
		result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
Clinical Performance	<p><u>Accuracy:</u> Accuracy against a Carbon Monoxide Monitor reference method indicated a relative sensitivity of 93.6% and a relative specificity of 74.0%</p> <p><u>Total Imprecision:</u> Percent rate CVs across 4 levels of analyte concentration (300 ng/mL-5000 ng/mL) were ≤ 1.09%.</p>	<p><u>Accuracy:</u> Accuracy against a GC/MS reference method was 98% (110 true positives, —80 true negatives)</p> <p><u>Total Imprecision:</u> Percent rate CVs across 3 levels of analyte concentration (300 ng/mL, 500 ng/mL, and 700 ng/mL) were ≤ 0.8%.)</p>

Brief Discussion of Nonclinical/Clinical Data (21 CFR 807.92(b)(1, 2))

The DRI[®] Cotinine EIA Assay was evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of sensitivity, linearity, specificity, precision, and accuracy.

The assay showed good sensitivity with an LOD of 34 ng/mL.

Precision studies indicated good reproducibility of results at the critical points of the measurement range (distinguishing positive from negative interpretations), as dose %CVs for both total and within-run testing were ... 9.4%.

Accuracy studies showed good performance of the DRI[®] Cotinine EIA Assay as compared to the GC/MS reference method. The % Total Agreement is 98%.

Specificity testing demonstrated that the DRI[®] Cotinine EIA Assay is not affected by common endogenous substances, variations in urinary pH levels, structurally unrelated pharmaceutical compounds, or potentially cross-reacting compounds.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))

The DRI[®] Cotinine EIA Assay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Director of Product Development
Microgenics Corporation
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MAY 22 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: k030649
Trade/Device Name: DRI[®] Cotinine EIA Assay
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT, MKU
Dated: February 27, 2003
Received: February 28, 2003

Dear Ms. Anne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

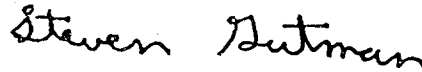
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

Page 2 –

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, stylized 'S' and 'G'.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): _____

Device Name: DRI® Cotinine Enzyme Immunoassay

Indications For Use:

“The DRI® Cotinine Enzyme Immunoassay is intended for the Qualitative and Semi-Quantitative determination of Cotinine in human urine at a cutoff level of 500 ng/mL. This assay is intended for in vitro diagnostic use only. The assay is intended as an aid in the detection of cotinine after use or exposure to tobacco products.”



Division Sign-Off

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

510(k) K030649

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)